DETAILED ACTION

1. This action is in response to the papers filed September 15, 2008, March 12, 2009, September 11, 2009. This action is made FINAL.

Applicant's election with traverse of SEQ ID NOs: 457-467 in the reply filed on September 15, 2008 is acknowledged. The traversal is on the ground(s) that the Applicants believe that the Examiner has not met the burden of establishing two or more independent and distinct inventions claimed in one application and that the search poses an undue burden on the Office. This argument has been fully considered but is not persuasive. The claims encompass a multitude of distinct nucleic acid sequences as well as all possible combinations of two or more nucleic acid sequences. Specifically the claims encompass two or more nucleic acid sequences selected from a group consisting of ~150 different SEQ ID NOs. A search of the claims would require ~150 separate sequence searches and consideration of any prior art relevant to each sequence searched. The ~150 different nucleic acid sequences encompassed by the claims, and the various combinations of two more sequences also encompassed by the claims, differ in sequence and structure from one another, and possess different functional properties and characteristics. In accordance with the policy set forth in 1316 OG 122 (27 March 2007), claims directed to polynucleotide molecules are considered for independence, relatedness, distinction, and burden as for claims to any other type of molecule. In the instant case, the nucleic acid sequences of each constitute a distinct

invention. Further as each combination of two or more sequences would require a different sequence search, a search of more than one such combination would pose a serious burden on the examiner and on the Office. The requirement is still deemed proper and is therefore made FINAL.

Further it is noted that in the papers filed March 12, 2009 the Applicants renumbered the sequences in the sequence listing because SEQ ID NOs: 97 and 326 did not have any nucleotide sequences associated with them. The sequences elected by the Applicants (SEQ ID NOs: 457-467) were renumbered as SEQ ID NOs: 455-465.

2. Claims 1-37 are currently pending.

Claims 2, 36, and 37 have been amended.

Claims 1-20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 1, 2007.

Further the SEQ ID NOs: listed in claims 36 and 37 (other than the elected SEQ ID NOs: 455-465) have been withdrawn from further consideration as being drawn to a nonelected subject matter.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a new ground of rejection necessitated by amendment

Claims 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-37 are rejected over the recitation of the phrase "wherein the SNPs include the nucleic acid sequences selected from the group consisting of SEQ ID NOs: 455-465". In the instant case it appears that the nucleic acid sequences of SEQ ID NOs: 455-465 do not actually contains a SNP as stated in the claims. Rather it appears based on the specification that these sequences comprise a tag sequence and a primer sequence that binds adjacent to a SNP. This rejection maybe overcome by amending the claims to recite i.e., wherein the SNPs are detected by using primers consisting of the nucleic acid sequence of SEQ ID NOs: 455-465.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21-25, and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill (Int J Legal Med Pub 4/2001).

Regarding Claims 21 and 22 Gill teaches a method wherein a blood stain from a crime scene was analyzed (page 205, col 1). In the instant case the blood stain is being interpreted as a sample of compromised nucleic acids because the specification (page 11) defines a compromised nucleic acid sample as a sample known to contain or suspected to contain nucleic acids wherein the nucleic acids of the sample are too degraded, and dried blood stains are reasonably suspected to contain degraded DNA. Thus Gill teaches a method of obtaining a sample of compromised nucleic acids. Gill further teaches that the sample was genotyped using an array of biallelics (SNPs), wherein the array can comprise up to several hundred loci (page 204, col 2), therefore this array would be able to identify two or more SNPs in the sample. Gill also teaches comparing the identity of the SNPs in the compromised sample with a panel comprising two or more SNPs. For example in instances when the contributors to the sample are a suspect and an unknown individual, Gill teaches that the genotype of the sample can be compared to the genotype of the suspect and to the genotype of the unknown (page 205, col 1). Further these SNPs are not genetically linked with respect to one another (since he discloses several hundred loci) and are located outside of tandem repeat nucleic acid sequences. It can be inferred that these SNPs are not STR since Gill distinguishes SNPs from STR (page 204).

Regarding Claim 23 Gill teaches a genotyping method wherein the single nucleotide polymorphisms are biallelic (page 204, col 2). Gill does not specifically state

that the alleles of the SNPS are T and/or C, however if several hundred loci are typed it is inherent that some alleles will be T alleles and some will be C alleles.

Regarding Claims 24 and 25 Gill discloses a method of analyzing SNPs for forensic purposes. Gill discloses an example of a typical rape case wherein the mixture comprises contributions from the victim and the suspect (page 206, col 2). Thus Gill teaches a method wherein the population of interest is human and wherein the sample comprises human nucleic acids.

Regarding Claims 27- 28 Gill teaches a method wherein the two or more single nucleotide polymorphisms present in the compromised nucleic acid sample are identified using an array. In the instant case arrays are considered to be multiplexed reactions since the array format allows for several loci to be examined at once.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Shultz (US Patent 6235480 Issues 5/2001).

The teachings of Gill are presented above.

Gill does not teach a method wherein the SNPs in the sample are identified using a single base primer extension reaction.

However Shultz teaches that single base extension is a technique that allows the detection of SNPs by hybridizing a single strand DNA probe to a captured DNA target. Once hybridized the single strand probe is extended by a single base with labeled dideoxynucleotides which can be detected (column 4, lines 5-12).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by detecting the SNPs using a single base primer extension reaction as suggested by Shultz. Using single base extension reactions as a method to detect SNPs was routinely used in the art at the time of the invention as demonstrated by Shultz. Thus one of skill in the art could have combined the methods of Gill and Shultz, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention.

8. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Koster (US Patent 6133436 Issued 10/2000).

The teachings of Gill are presented above.

Gill does not teach a method wherein the array is an addressable array or a virtual array.

However Koster teaches arrays that are addressable (Col 9, line 45-54). Koster also teaches beads linked to solid supports (Abstract). In the instant case this is being interpreted as a virtual array since the specification (page 29) defines a virtual array as a suspension of microspheres.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by using an addressable array as suggested by Koster for the benefit of being able to tell the identity of each nucleic acid on the array based on its location. Further it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by using a virtual array as suggested by Koster because these arrays compared to flat arrays provide an increased surface area for immobilization of nucleic acids (abstract). In the instant case each of the claim limitations were known, thus one of skill in the art could have combined the methods of Gill and Koster, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention.

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Jehaes (Int J Legal Med Pub 12/2001).

The teachings of Gill are presented above.

Gill does not teach a method wherein the compromised nucleic acid sample is amplified to a length of from about 10 nucleotides to about 100 nucleotides.

However Jehaes teaches when analyzing forensic DNA samples they found that by selecting primers which amplified short fragments, they were able to detect polymorphisms which were undetected using primers which amplified longer fragments. This was attributed to DNA degradation that occurred after sampling (Abstract). Jehaes concludes that the use of short PCR fragments <200 bp (which encompasses fragments between 10 and 100 bp) in all forensic cases should improve DNA analysis and increase the success rate of analysis (page 140, col 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by amplifying the compromised nucleic acid sample to produce short fragments as suggested by Jehaes for the benefit of being able to detect polymorphisms that were undetectable using longer fragments due to DNA degradation of the sample.

The following is a new ground of rejection necessitated by amendment

10. Claims 32-33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Suomalainen (Molecular Biotechnology 2000 Vol 15 pages 123-131).

The teachings of Gill are presented above.

Gill does not teach a method wherein 12 to 40 SNPs are identified and compared to obtain the genotype for the compromised nucleic acid sample (clms 32-33).

However Suomalainen teaches that they have developed a system for forensic DNA typing, in which a panel of 12 SNPs is analyzed (page 124, col 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by using a relatively small array of 12 to 40 SNPs as suggested by Suomalainen. Using a panel of 12 SNPs for forensic DNA typing was well known in the art at the time of the invention as demonstrated by Suomalainen. One of skill in the art would have been motivated to use a panel of 12 SNPs particularly since Suomalainen teaches that a panel of 12 SNPs is effective for forensic DNA typing.

The following is a new ground of rejection necessitated by amendment

11. Claims 32-33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Suomalainen (Molecular Biotechnology 2000 Vol 15 pages 123-131).

The teachings of Gill are presented above.

Gill does not teach a method wherein 12 to 40 SNPs are identified and compared to obtain the genotype for the compromised nucleic acid sample (clms 32-33).

However Suomalainen teaches that they have developed a system for forensic DNA typing, in which a panel of 12 SNPs is analyzed (page 124, col 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by using a relatively small array of 12 to 40 SNPs as suggested by Suomalainen. Using a panel of 12 SNPs for forensic DNA typing was well known in the art at the time of the invention as demonstrated by Suomalainen. One of skill in the art would have been motivated to use a panel of 12 SNPs particularly since Suomalainen teaches that a panel of 12 SNPs is effective for forensic DNA typing.

The following is a new ground of rejection necessitated by amendment

12. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Lander (WO 98/20165 Pub 5/1998) and McIntosh (US 2002/0094525 Pub 7/2002 and Filed 12/1999).

The teachings of Gill are presented above.

Gill does not teach a method wherein only SNPs that are not genetically linked with respect to one another and are located outside tandem repeat nucleic acid sequences are identified and compared to obtain the genotype for the compromised nucleic acid sample (clms 34-35).

However Lander teaches using SNPs for forensic analysis. Lander teaches that the more sites that are analyzed, the lower the probability that the set of polymorphic forms in one individual is the same as that in an unrelated individual. Preferably if multiple sites are analyzed the sites are unlinked. Thus polymorphisms of the invention are often used in conjunctions with polymorphisms in distal genes (page 15 lines 6-15).

Further McIntosh teaching SNPs for determining identity. McIntosh teaches that SNPs are defined by the following attributes. A central attribute of such a polymorphism is that it contains a polymorphic site, X, which is the site of variation between allelic sequences. A second characteristic of a SNP is that its polymorphic site X is frequently preceded by and followed by invariant sequences of the allele (0030). An invariant sequence of an allele is a sequence that does not vary in the population of species. In the instant case tandem repeat nucleic acid sequences are not considered to be invariant since they have high mutation rates (para 0030, 0031, 0040). Thus McIntosh teaches that SNPs are located outside tandem repeat nucleic acid sequences.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by using only SNPs that are not genetically linked with respect to one another and are located outside tandem repeat nucleic acid sequences are identified as suggested by Lander and McIntosh. As demonstrated by Lander and McIntosh using only SNPs that are not genetically linked with respect to one another and are located outside tandem repeat nucleic acid sequences are identified was well known in the art at the time of the invention for forensic analysis. One of skill in the art would have been motivated to use only SNPs that are not genetically linked with respect to one another and are located outside tandem repeat nucleic acid sequences are identified in order to achieve the advantages of using SNPs in genetic analysis such as: SNPs occur at a greater frequency and with greater uniformity than STRs and VNTRs, SNPs are more stable than other classes of polymorphisms, SNPs have the advantage that their allelic

frequency can be inferred from the study of relatively few representative samples, SNPs reflect the highest possible definition of genetic information, and SNPs can be characterized easily using a variety of different methods (see McIntosh paras 0037-0044).

13. The prior art does not teach or suggest the nucleic acid sequences of SEQ ID NO: 455-465.

Response To Arguments

14. In the response filed March 12, 2009, the Applicants traversed the art rejections based on Gill. The Applicants argue that Gill says nothing about selecting SNPs that are not genetically linked respect to one another and SNPs that are located outside tandem repeat nucleic acid sequences.

This argument has been fully considered but is not persuasive. While Gill exemplifies using small arrays of 50-150 SNPs for forensic analysis Gill also discloses arrays consisting of hundreds of SNPs. It would be a property of an array consisting of several hundreds of SNPs that not all of the SNPs would be genetically linked to one another. Additionally the instant specification (page 12) teaches that "not genetically linked with respect to one another" means that the SNPs are selected to be a desirable distance apart from one another. So even if the 150 SNPs of Gill occurred consecutively on the same nucleic acid strand SNP #1 would still be 150 base pairs from SNP #150 and 150 base pairs can be interpreted as a desirable distance. Further it can be

inferred that these SNPs are not located in tandem repeat nucleic acid sequences since Gill distinguishes SNPs from STR. For these reasons the rejections are maintained.

Regarding the additional references the Applicants argue that the addition references do not teach what is missing in Gill.

The applicants arguments' regarding what is missing in Gill have been fully addressed above. The response to applicant's arguments, as set forth above, applies equally to all of the rejections based on Gill.

Conclusion

15. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Examiner
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/Stephen Kapushoc/

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